Questions from Senator Hassan:

Dr. Hahn:
1. I strongly agree with your comments this morning on the importance of Americans trusting FDA as the gold standard for protecting public health.

For millions of parents with children who are nicotine dependent because of e-cigarettes, that trust took a hit this week when they watched the president cave to special interests and reverse his commitment to address the youth e-cigarette epidemic.

Whether it's Purdue Pharma influencing the approval and marketing of OxyContin, or DC lobbyists dictating FDA's response to the youth e-cigarette epidemic, the public may lose faith in FDA when they see decisions being driven by corporate special interests instead of facts and science.

How will you ensure that every decision made under your leadership is based on facts and science, and what will you do if one of your decisions is overruled by political consultants or corporate lobbyists?

Response: As I stated in the hearing, throughout my career, whether it was at the patient's bedside or as a medical executive, I've made decisions based upon data and science, congruent with the law. Nothing is more important for a patient than for them to trust that you are making a decision that's in their best interest and no one else's interest. And I commit to you that science, data and the law will guide decisions that I would make if I'm fortunate enough to be confirmed by the Senate as Commissioner of Food in Drugs. I pledge to represent faithfully the decisions made by the Agency which, as stated above, will be based upon data, science and the law.

2. Reports that the administration caved to corporate special interests in reversing the e-cigarette flavor ban are incredibly disturbing.

If confirmed, you will oversee the FDA Premarket Tobacco Application process for e-cigarettes. Parents, teachers, public health advocates, and members of this Committee will be counting on you to protect the integrity of that process.

As Commissioner, will you publically disclose all meetings between FDA and Juul that take place before and during the Premarket Tobacco Application process, including who attended and what was discussed?

Response: FDA has a very transparent process for accepting and disclosing meetings. I look forward to continuing that tradition.

And will you provide this Committee with any data you receive from companies like Juul that relate to youth e-cigarette use, including data on flavors and diversion?

Response: I will disclose all data requested of the Committee, consistent with legal an ethics requirements.

3. The FDA encouraged development of 'abuse-deterrent' opioids by approving products on an accelerated approval pathway.

We know that these abuse-deterrent opioids are no less addictive than other products on the market, and can be abused.

FDA requires that drug manufacturers submit post-market data, but often fails to hold them accountable for meeting submission deadlines.

This problem is not limited to opioids. Manufacturers of high-cost drugs often fail to comply with post-market reporting requirements, and in some cases we learn years later that the drug was ineffective.

If confirmed, what actions will you take to ensure that drug manufacturers meet their post-market reporting deadlines?

How will you ensure that FDA takes swift action based on post-market data, including revoking approval of drugs where appropriate, if post-market data shows a drug is unsafe or clinically ineffective?

Response: The data provided in post-market reporting is critical to ensuring the enduring safety, efficacy and overall patient benefit the gold standard of the FDA delivers. I commit to using science and data to drive decision-making, which includes leveraging these data to take swift action on products if they are no longer living up to their promise.

4. Since 2001, FDA has been asked by stakeholders to consider removing chronic pain from the label of opioid products.

What is your position on labeling opioids such as OxyContin as appropriate for patients managing chronic pain?

5. Officials from the Centers for Disease Control and Prevention, Department of Defense, and Department of Veterans Affairs have stated that the risks of opioid therapy for chronic conditions such as headaches, fibromyalgia, and chronic back pain likely outweigh the benefits.

Do you agree? Can you explain your position on how best to move forward with labeling, marketing and prescribing guidelines for opioids to ensure patient safety?

6. The Centers for Disease Control and Prevention126, Department of Defense, and Department of Veterans Affairs127 have warned against prescribing opioids at doses that exceed 90mg morphine equivalents per day.

Response to 4-6. Thank you for this question. I believe science and data should inform FDA's actions. My own personal experience with this issue is as a cancer doctor. I have known patients who have survived cancer only to become addicted to opioids. For many years, our medical education was that addiction did not occur in cancer patients and we were encouraged to use opioids liberally. This turns out not to be the case and unfortunately, there have been tragic consequences. There has been a significant change based upon doctor education efforts in the prescribing habits for opioids. I refer my patients to a supportive care team that provide evidence-based pain care. If confirmed, I look forward to reviewing the science and data on opioid labeling. While patient care must be provided on an individualized basis, I agree that providers should be cautious in prescribing opioids, especially in high doses. The prescribing guidelines from the

Centers for Disease Control and Prevention have transformed opioid prescribing in recent years, but much remains to be done.